UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,349	01/09/2006	Sarah C. Bodary Winter	P1988R1	4763

9157 7590 09/20/2007

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,349	BODARY WINTER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9-11 and 14-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/25/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election of Group II invention, claims 9-11 and 14-17 directed to SEQ ID NO:20, filed on 13 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment filed on 13 July 2007 is acknowledged and entered. Following the amendment, claims 1-8, 12, 13 and 18-25 are canceled, and claim 9 is amended.

Currently, claims 9-11 and 14-17 are pending, and will be examined to the extent that they read on the elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 8/4/05 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application is a national stage entry (371) of PCT/US03/27382 with the international filing date of 8/28/03, which is acknowledged.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claims

Claim 10 is objected to for the following informalities, appropriate correction is required for each item:

The claim recites "*a* polypeptide according to claim 9", "the" is suggested to replace "a".

Claims 14, 16 and 17 are objected to for encompassing a non-elected subject matter, parts (c) and (d). The applicant is required to amend the claims to read only upon the elected invention.

Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated polypeptide having an amino acid sequence of SEQ ID NO:20, does not reasonably provide enablement for claims to claims to any variant of SEQ ID NO:20 (claim 9, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 9-11 and 14-17 are directed to an isolated polypeptide having the amino acid sequence of SEQ ID NO:20, a % variant ("at least 80%"), a fusion protein and a composition thereof. The polypeptide is designated PRO84197.

The specification discloses a polynucleotide of SEQ ID NO:19, which encodes a human polypeptide, PRO84197 of SEQ ID NO:20. The specification discloses that the encoding nucleic acid of PRO84197, along with another 23 nucleic acids, are expressed higher in psoriasis PBMCs than in normal PBMCs as tested in a microarray analysis, and the specification further concludes that the nucleic acids and encoded proteins of Figures 1-48 are expressed higher in psoriasis PBMCs than in normal PBMCs as tested in a microarray analysis (Example 1). While

the specification indicates that the proteins along with secreted proteins encoded by the genes amplified in psoriasis find use in the diagnosis and prognosis of this disease (page 72, lines 16-18), it does not disclose any characteristics other than the sequences, nor any functional property of the PRO84197 polypeptide. Thus, there is no variants of the polypeptide with any functional activity can be identified as there is nothing can be tested with this regard. Further, the specification does not teach any variant of the PRO84197 meeting the limitation of the claims, or any variant that is also found in psoriasis. The specification provides no guidance or working examples as to how the skilled artisan could identify (make) a variant associated with psoriasis, or use a variant with at least 80% sequence identity to SEQ ID NO:20, as no variant of SEQ ID NO:20 has been identified in psoriasis, and no functional activity has been identified for the PRO84197 of SEQ ID NO:20. There is no evidence of the actual conception of such polypeptide variants, nor is there any evidence of record that they exist in psoriasis so that they can be used for the purpose of diagnosis. Further, *even if* such variants existed in psoriasis, what might happen in psoriasis regarding genetic variations to the polypeptide of SEQ ID NO:20 are completely unpredictable. Therefore, there is no way for a skilled artisan to imagine the detailed structure of the encompassed variants, and to make such variants. Clearly, undue experimentation would be required prior to make and use the invention in a manner commensurate in scope with the claims.

Due to the large quantity of experimentation necessary to identify variants in psoriasis, and to determine how to use any variant encompassed by the claims, the lack of direction/ guidance presented in the specification regarding same, the absence of working examples directed to same, the complex and unpredictable nature of the invention, and the breadth of the claims which embrace a broad class of structurally diverse variants of SEQ ID NO:20 without a functional limitation or a particular association with psoriasis, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 9-11 and 14-17 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-11 and 14-17 encompass variant polypeptides having at least 80% sequence identity with a particular disclosed sequence, SEQ ID NO:20. The claims do not require that the encoded polypeptides possess any particular biological activity (as none has been identified), nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity. The specification discloses an amino acid sequence of human PRO84197 with SEQ ID NO:20. No variants thereof meeting the limitation of the claims were ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial amino acid structure in the form of a recitation of percent identity (for % variants). There is not even structural identification of the polypeptide from which variants are derived, or identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, with the exception of SEQ ID NO:20, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of the polypeptide variants, and therefore conception is not achieved, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids encoding the amino acid sequence set forth in SEQ ID NO:20, but not the full breadth of the claims (% variants) meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specific known activity. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fukushima et al. (US7,189,546) discloses an amino acid sequence, which amino acid sequence comprises amino acid residues 2-28 of the present SEQ ID NO:20 with 48.1% sequence similarity (see computer printout of the search results).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/14/07